PHARMACY EXAMINING BOARD MINUTES MADISON, WI APRIL 9, 2003

PRESENT: Michael Bettiga, R.Ph. (telephone); John Bohlman, R.Ph., Dan Luce,

R.Ph. (telephone); Georgina Forbes, Susan Sutter, R.Ph.

EXCUSED: Cynthia Benning, R.Ph., Charlotte Rasmussen

STAFF PRESENT: Thomas Ryan, Bureau Director, Deanna Zychowski, William Black, Legal

Counsel; Grace Schwingel, Executive Staff Assistant; and Division of

Enforcement Staff for portions of the meeting.

GUESTS: The Honorable Sheldon Wasserman, State Representative; Jackie Dicks,

Aide to the Honorable Carol Owens, State Representative.

CALL TO ORDER

The meeting was called to order at 9:00 a.m. by Susan Sutter, Chair. Quorum was confirmed.

AGENDA

Additions/Changes to the Agenda:

Chairperson Sutter tabled items E and F of the agenda until the May meeting. An updated inspection report was added.

An amended item B. i. was added.

MOTION: John Bohlman moved, seconded by Georgina Forbes, to approve the

agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF MARCH 11, 2003

Corrections to Minutes:

Page 7 - Correction to spelling of Marshland.

Page 6 - Mike Bettiga noted he abstained from voting on the Oestrich monitoring case.

Page 6 - The last sentence should read: "The Morton Pharmacy would like to allow patients to pick up prescriptions at the Pitney Bowes worksite within the confines of the health clinic there." Page 11 - Strike Motion validating examination results. The Board only met with Casey on

examination issues. No examination results were validated.

MOTION: John Bohlman moved, seconded by Georgina Forbes, to approve the

minutes of March 11, 2003, as amended. Motion carried unanimously.

Assembly Bill 63

Tom Ryan informed the Board that Assembly Bill 63 is currently in the Assembly Labor Committee.

Assembly Bill 67

Jackie Dicks, an aide to The Honorable Carol Owens, informed the Board that a hearing was held on March 5, 2003 for Assembly Bill 67. It is currently awaiting executive session.

John Bohlman asked about the Board's preference with respect to his current status as the Board's legislative liaison and his role in conveying Board actions to the legislature. He requested that a member of the management team attend the May meeting to discuss the Board's relationship with the Department, to discuss issues of mutual concern, including communication with the Board and the legislature. Chairperson Sutter also requested a member of the new management team attend the May meeting to clarify roles of the Board and the Department following the transition.

Following discussion of the bills, the Board re-stated its position on Assembly Bill 63, Assembly Bill 67 and Senate Bill 21, as recorded in the April 2003 minutes following discussion of Senate Bill 21, via a motion offered by Mike Bettiga and seconded by Dan Luce. John Bohlman requested a roll call vote:

MOTION:

A pharmacist has the right to exercise professional judgment to refuse to fill a prescription, and the board believes the pharmacist should not be the subject of adverse employment action because of it. However, the Board does not believe that the bills are phrased appropriately to encompass that right because it is too narrowly drawn for these specific instances. Adopted by roll call vote. Mike Bettiga - aye; Georgina Forbes – aye; Dan Luce – aye; Sue Sutter - aye. Motion carried unanimously.

DOE REPORT – 2002 PHARMACY INSPECTIONS

Alfred Hall and Dave O'Connell of the Division of Enforcement reviewed the inspection report for 2002. Dave O'Connell stated that there appears to be a number of repeat violations clustered together by type. John Bohlman indicated that he has recognized a tendency by pharmacies to indicate compliance when compliance has not been attained. In the future there will be an effort to include with application packets, prior to inspections, a letter communicating the reported findings of inspectors and urging applicants to pay particular attention to areas of vulnerability revealed by the reports. Dave O'Connell will prepare a letter for discussion at a future meeting. Alfred Hall stated there were relatively fewer significant violations, with the most common violation being an erroneous address on a prescription. Dave O'Connell added that 66 of 102 inspections revealed non-compliance, with cases being opened in 10% of them. Chairperson Sutter underlined the importance of the statute, the self-inspection and follow-up audit.

John Bohlman stated an additional concern related to pharmacies is not keeping current their poison books. He asked that the Department report to the Board on monitoring the distribution and sale of poisons, not restricted to pharmacies, in the context of the Homeland Security initiatives.

REVIEW VARIANCE AND RE-MODEL INFORMATIONAL PAGES FOR DRL WEB

Kris Hendrickson discussed informational sheets she created for distribution on the Department's web-site to clarify how pharmacies should proceed on re-models and on variance requests. Chairperson Sutter suggested that at the top of the request for remodel page, the document states that a remodel may not begin until confirmation and approval is received from the Board office, but #7 states a self-inspection report must be submitted prior to approval. Self-inspection should be performed after a re-model. William Black, Legal Counsel, stated that clarification could be made to distinguish between "shadow" pharmacies and permanent pharmacies. Shadow pharmacies are alternate professional service areas which are used when a self-inspection would be required before the permanent space is re-modeled. Chairperson Sutter suggested allowing approval for a shadow pharmacy by a process similar to that of a new pharmacy and Dan Luce suggested a time limit be imposed. Discussion was suspended at 10:15 a.m. for Representative Wasserman's discussion of AB 11.

Assembly Bill 11 - The Honorable Sheldon Wasserman

Assembly Bill 11 relates to partner-delivered therapy, an effort to allow physicians, physician assistants and nurse practitioners to prescribe an extra antibiotic drug dosage for use of a patient's sexual partners for the treatment of certain sexually transmitted diseases. Because of embarrassment, partners of patients who seek treatment for STD infection often will not seek treatment on their own. He noted that California (2001) passed a similar law and Tennessee recently amended its physician practice rules to allow for the practice.

Representative Wasserman reviewed three amendments brought to him by the Pharmacy Society of Wisconsin. The amendments clarify that the pharmacists would not be responsible for the bill or have legal liability in prescribing the medication. As a practicing physician, Dr. Wasserman has written scripts for partner-delivered therapy because of its public health impact. Chairperson Sutter expressed concern with the absence of a patient-physician relationship and with permissive language in the first section of the bill because it does not hold the prescriber accountable for communicating with the unnamed patient, who will not receive a consultation. William Black stated that it appears to be a directive for the patient to contact his or her health department with questions. Representative Wasserman stated that the language reflects the practitioner's recognition of liability concerns. John Bohlman stated that the pharmacist is not given the benefit of tracking the unnamed patient for allergies and other problems that may arise and that for this and other reasons liability of the pharmacist must be addressed. Representative Wasserman stated further that prescribers want to assume the risk of liability and William Black suggested that a specific release of liability would have to be written into statute.

Mike Bettiga signed off after the discussion. Dan Luce was called back after break.

REVIEW VARIANCE AND RE-MODEL INFORMATIONAL PAGES FOR DRL WEB (CONTINUED)

The Board decided that Kris Hendrickson and William Black would re-draft #7 on the informational sheet to reflect current policy; that is, a self-inspection must be performed on the permanent re-model after it is completed. If there is a temporary pharmacy with it, a self-inspection must be done prior to completion of the permanent re-model. John Bohlman asked that further educational information be included on the informational sheets, such as the need for a variance request to be sent to the Board at least two weeks prior to the Board meeting and inclusion of the specifics of the variance. The re-drafted informational item will be presented at the May meeting.

ITEMS E AND F WERE TABLED UNTIL THE MAY MEETING

PROPOSED ADMINISTRATIVE RULE ADOPTIONS FOR BOARD CONSIDERATION AND POSSIBLE ACTION

MOTION: John Bohlman moved, seconded by Dan Luce, to approve Clearinghouse

Rule 02-140. Motion carried unanimously.

MOTION: Dan Luce moved, seconded by Georgina Forbes, to approve

Clearinghouse Rule 02-150. Motion carried unanimously.

MOTION: Georgina Forbes moved, seconded by Dan Luce, to approve

Clearinghouse Rule 03-005. Motion carried unanimously.

VARIANCE REQUEST – MARSHFIELD CLINIC

MOTION: John Bohlman moved, seconded by Dan Luce, to grant the variance

request. Motion carried unanimously.

VARIANCE REQUEST - RIVERVIEW HOSPITAL ASSOCIATION

The additional information received by Riverview Hospital Association regarding its proposed physician dispensing system for a cencer center inside Riverview Hospital was reviewed by the Board. The Board raised several questions that require a personal appearance by Ms. Breckheimer. Ms. Breckheimer will be invited to the May meeting of the Board.

VARIANCE REQUEST – MORTON PHARMACY

Kurt Holm, Director of Morton Pharmacy, appeared to clarify information for the Board regarding his variance request. He presented a response to the Board's questions from the past month. The Board confirmed that there will be no removal of the drugs from the pharmacy if a consultation has not occurred. Mr. Holm will send a copy of the procedures and all the licenses where the variances will apply so that they can be included in the variance folders.

MOTION: Dan Luce moved, seconded by John Bohlman, to approve the variance

request. Motion carried unanimously.

REVIEW OF DISTRIBUTOR APPLICATION CURASCRIPT PHARMACY

The Board discussed the application, noting that a discipline in Florida was based on the lack of a pharmacy license.

MOTION: John Bohlman moved, seconded by Dan Luce, to grant the distributorship.

Motion carried unanimously.

REVIEW OF DISTRIBUTOR APPLICATION – VISITING NURSING HOME MEDICAL SERVICES

MOTION: John Bohlman moved, seconded by Georgina Forbes, that if Visiting

Nursing Home meets all criteria for licensure prior to being granted a license they should be granted a license. The file will be referred to DOE.

Motion carried unanimously.

REVIEW OF MANUFACTURER SELF-INSPECTION REPORT

MOTION: John Bohlman moved, seconded by Georgina Forbes, to approve the self-

inspection report as distributed. Motion carried unanimously.

PRACTICE QUESTIONS

Calumet Medical Center

The Board reviewed the material and decided by unanimous consensus that a flow chart is needed to explain the system at the May meeting.

REPORT OF CONTROLLED SUBSTANCES BOARD – CYNTHIA BENNING, CSB CHAIR

Tabled until May in Cindy Benning's absence.

REPORT ON WISCONSIN PHARMACY FORUM - SUE SUTTER

Chairperson Sutter noted that the Forum was held on April 3, 2003, and will have a draft summary of the report for the May meeting.

INFORMATIONAL ITEM

Sue Sutter briefed the Board about a conflict between the NABP Letter of Agreement with the Board and Wisconsin's rules that was discovered on April 8, 2003. Wisconsin law allows a student to take the NAPLEX examination within 60 days of graduation while the Letter of

Agreement mandates completion of all requirements of graduation prior to taking the exam. The Board and the Department were in the process of resolving the conflict.

ADJOURN TO CLOSED SESSION

MOTION: John Bohlman moved, seconded by Dan Luce, to adjourn to closed session

pursuant to Wisconsin State Statutes § 19.85 (1) (a), (b), (f) and (g) at 11:38 a.m. Motion carried by roll call vote: John Bohlman – yes;

Georgina Forbes – yes; Dan Luce – yes; Susan Sutter – yes.

RE-CONVENE TO OPEN SESSION

MOTION: Georgina Forbes moved, seconded by John Bohlman, to re-convene to

open session at 2:00 p.m.

02 PHM 059

MOTION: Mike Bettiga moved, seconded by Georgina Forbes, to return 02 PHM 059

to the Division of Enforcement for further consideration. Motion carried

unanimously.

03 PHM 004

MOTION: Mike Bettiga moved, seconded by Georgina Forbes, to close 03 PHM 004

for no violation. Motion carried unanimously.

MARK ANDERSON – REQUEST FOR 3-MONTH STAY AND MODIFICATIONS

MOTION: Mike Bettiga moved, seconded by John Bohlman, to grant the 3-month

stay and deny the reduction in audits. Motion carried unanimously.

ROBERT GUZZETTA - REQUEST FOR 3-MONTH STAY

MOTION John Bohlman moved, seconded by Georgina Forbes, to grant the 3-month

stay with reduction to monthly therapy. Motion carried unanimously.

WILLIAM KARWOSKI – FOLLOWUP TO REQUEST FOR MODIFICATIONS (REVIEW INFORMATION FROM THERAPIST)

MOTION: Mike Bettiga moved, seconded by John Bohlman, to allow for 4 hours as

pharmacist-in-charge without open or close. Urine screens requust denied.

Motion carried unanimously.

MARILYN KUHRT - REQUEST FOR FULL LICENSURE

MOTION John Bohlman moved, seconded by Mike Bettiga, to grant full licensure.

Motion carried unanimously.

JOHN LITZENBERG - REQUEST FOR 3-MONTH STAY AND MODIFICATIONS

MOTION: John Bohlman moved, seconded by Mike Bettiga, to grant the request for

a 3-month stay and an additional 8 hours of pharmacy-in-charge at Walgreens. Request for managing pharmacist privileges denied. Motion

carried unanimously.

DUANE OESTREICH – REQUEST FOR 3-MONTH STAY

MOTION: John Bohlman moved, seconded by Georgina Forbes, to grant the 3-month

stay. Motion carried unanimously.

KEVIN PAMPUCH – REQUEST FOR 3-MONTH STAY

MOTION: John Bohlman moved, seconded by Mike Bettiga, to grant the request for

a 3-month stay. Motion carried unanimously.

JOHN SCHMITT - REQUEST FOR MODIFICATION OF ORDER

Tabled until the next meeting.

GREGORY TECHE – REQUEST FOR MODIFICATION OF ORDER

MOTION: Mike Bettiga moved, seconded by John Bohlman, to deny the request for

modification of the order. Motion carried unanimously.

DELIBERATION OF PROPOSED ADMINISTRATIVE WARNING

002-PHM-100

MOTION: John Bohlman moved, seconded by Mike Bettiga, to accept the proposed

administrative warning. Motion carried unanimously.

EXAMINATION ISSUES

MOTION: John Bohlman moved, seconded by Georgina Forbes, to validate the

examination scores entered April 9, 2003. Motion carried unanimously.

INFORMATIONAL ITEMS

Discussion continued on the NAPLEX examination issue with Kris Hendrickson present to brief the Board. No action was taken. A DHHS warning letter and the monthly drug theft and loss report are noted as additional informational items.

ADJOURNMENT

MOTION: Mike Bettiga moved, seconded by John Bohlman, to adjourn the meeting

at 2:50 p.m. Motion carried unanimously.